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Revision: 13	Replaces: 04/01/08	Effective: 07/01/08

1. <u>Purpose</u>:

To provide standard procedures for the receipt, storage, archiving, and disposal of USDA/AMS Pesticide Data Program (PDP) samples.

2. <u>Scope</u>:

This standard operating procedure (SOP) shall be followed by all laboratories conducting residue studies for PDP, including support laboratories conducting stability or other types of studies that may impact the program.

3. Outline of Procedure:

- 5.1 Sample Receipt
- 5.2 Sample Storage
- 5.3 Storage of Extracts
- 5.4 Storage of Reserve Samples
- 5.5 Disposal of Reserve Samples
- 5.6 Disposal of Extracts

4. References:

- USDA/AMS PDP QA/Technical Meeting, February 26-28, 2008, Crystal City, VA
- USDA/AMS-EPA Planning Meeting, March 14, 2001
- USDA/AMS PDP Quality Assurance(QA)/Technical Meeting, February 21-22, 2001
- PDP Program Plan, January June 2001
- Federal/State Meeting, October 31 November 2, 2000
- Memorandum to State PDP Laboratories from Dr. Robert Epstein, Science Division, AMS, May 22, 1991
- Memorandum to State PDP Laboratories from Dr. Robert Epstein, Science Division, AMS, April 25, 1991
- Good Laboratory Practice Standards 40CFR Parts 160.47 and 160.51, EPA, August 17, 1989

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5. Specific Procedures:

This SOP represents minimum PDP requirements and is presented as a general guideline. Each laboratory shall have written procedures that provide specific details concerning how the procedure has been implemented in that laboratory.

5.1 Sample Receipt

- **5.1.a** The sample is defined as the portion that the collector provides to the laboratory, usually between one and seven pounds. The acceptable weight range is plus or minus 20 percent of the target weight (e.g., for 5-lb samples: 4-6 lbs). Samples that weigh less than the lower end of the ranges are not acceptable. If the laboratory receives an unusually large sample (e.g., more than ten pounds) then the laboratory may randomly select the targeted weight of product (e.g., 5 pounds for oranges) to homogenize.
- **5.1.b** Samples shall be inspected upon arrival to verify that the sample is suitable for analysis based on commodity requirements (refer to current MPO Commodity Fact Sheet), checking that variety information that can be determined is recorded on the Sample Information Form (SIF), and that the information on the SIF and sample identification match each other. If a paper SIF is received, the laboratory shall fax a copy (or scan and email) to MPO within 24 hours.
- **5.1.c** If the sample container integrity is compromised, the proper amount of sample is not present, or the sample containers are not adequate, document this at the bottom of the SIF. Documenting date and time received on the SIF is also acceptable.
- **5.1.d** The units (i.e., pieces of individual produce per sample) shall be counted for all large non-clustered commodities (e.g., apples, cantaloupe, onions, pears, sweet potatoes, etc.) prior to discarding any damaged or inedible samples. Record the number of individual units for each sample in section 6 of the SIF.
- **5.1.e** Samples received in damaged condition shall be discarded and not analyzed. In general, a minimum of 50% of the sample, by weight or count, should be available for analysis after any inedibles are discarded in order for the sample to be considered viable. Sample condition upon arrival (e.g., good, or entire sample mushy unable to analyze) shall be documented on the SIF.

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- **5.1.e.1** Fresh fruit and vegetable containers shall be inspected upon arrival for any deteriorating condition (e.g., leaking sample container, mold visible through container) which would make the sample inedible or compromise sample integrity.
- **5.1.e.2** Canned commodities shall be free of large dents or punctures
- **5.1.e.3** Frozen commodities shall arrive at the laboratory in plastic bags sealed by the collectors. Frozen commodities shall be inspected to determine the extent of thawing during transit. The plastic bags sealed by the collectors shall be opened only if absolutely necessary to determine the condition of the sample(s).
- **5.1.f** Prepared fresh product (e.g., snipped green beans, chopped packaged lettuce) is acceptable as long as varieties are not mixed (e.g., washed, chopped lettuce is iceberg only and not a lettuce mix). The laboratory shall note that the product is prepared (e.g., washed, chopped, snipped) in the comments section of the SIF.
- **5.1.g** Each sample shall be assigned a unique laboratory identification number. The identification number shall be recorded on or affixed to samples and sample aliquots in a manner to ensure its legibility during handling and storage. This number shall also be recorded on the accompanying paperwork.
- **5.1.h** Each laboratory shall maintain a log of samples received. Suggested methods are:
 - **5.1.h.1** Each sample shall be logged into a bound notebook with ink. Minimum information for the logbook includes sample numbers, date and time received (unless documented on the SIF), and who received the sample. Other information may include commodity type, reference to analytical method, results, and date when results were reported.
 - **5.1.h.2** Computer logs are also acceptable. The laboratory shall assure that the records are verified on a routine basis, and that electronic storage of data follows acceptable practices. Refer to SOP PDP-DATA-08.
- **5.1.i** The receiving laboratory shall notify the appropriate collection coordinator (e.g., Sampling Manager) within five working days if any samples are missing or unacceptable.

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5.1.j The receiving laboratory shall notify MPO of any continuing unresolved sampling issues on a monthly basis.

5.2 Sample Storage

- **5.2.a** All refrigerators and freezers used for PDP samples shall have controlled access. A logbook for each refrigerator and freezer shall be maintained that details sample traffic and periodic temperature checks.
- **5.2.b** The temperature checks shall be made each working day, or the laboratory may use automatic temperature recording devices. Checks shall be recorded.
- **5.2.c** Samples shall be stored in refrigerators and freezers separate from standards.
- **5.2.d** Fresh fruits and vegetables still sealed in bags shall be refrigerated for a period not to exceed 72 hours (from the time of arrival) until the sample is homogenized.
- **5.2.e** Commodities normally stored by consumers at room temperature (e.g., in cans, jars, shelf-stable boxes, etc.) shall be stored in a clean, dry area at room temperature (approximately 22°C) or lower until the sample is homogenized.
- **5.2.f** Frozen commodities that have not thawed in transit (still cold to the touch) shall be held in the freezer at approximately 0°C or lower until the sample is homogenized.
- **5.2.g** Frozen commodities that thawed in transit (not cold to the touch) shall be refrigerated. If possible the sample should be homogenized within 24 hours (from the time of arrival); however refrigeration of the thawed commodity for a period not to exceed 72 hours (from the time of arrival) is acceptable.
- **5.2.h** If it is not possible to extract the sample after homogenization, then the homogenized samples may be held for a period not to exceed 72 hours at approximately -20°C or lower, or the homogenized sample may be held for longer periods of time at approximately -40°C or lower.

5.3 Storage of Extracts

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- **5.3.a** Extracts shall be stored at approximately 4°C or lower. In an internal SOP each laboratory shall establish procedures to assure or develop evidence that evaporation of the solvent since the last use is not occurring in sample extracts. Suggested procedures are weighing the extract plus the bottle/tube or recording/marking the volume of the extract using the calibration markings on the side of the bottle/tube.
- **5.3.b** Injection vials shall be prepared immediately before injection or may be held at approximately 4°C or lower before injection. Each laboratory shall, in an internal SOP, establish procedures for the number of re-injections per vial, as well as the maximum amount of time that a vial may be left at room temperature and still be injected.

5.4 Storage of Reserve Samples

- **5.4.a** The reserve portions of violative samples shall be retained at approximately -40°C or lower for at least 6 months after results are reported, or until further instructions are received from USDA/AMS, Manassas, VA, whichever comes first.
- **5.4.b** The reserve portion of all other samples shall be stored at approximately -40°C or lower until final QA review and successful RDE transmission.

5.5 Disposal of Reserve Samples

5.5.a The reserve sample may be discarded after time period(s) specified in section 5.4 have elapsed. Disposal shall be documented (e.g., in the freezer log or sample log) and shall contain at minimum date of disposal, sample number, and initials of the individual who discarded the sample.

5.6 Disposal of Extracts

5.6.a The extracts may be discarded after time period(s) specified in the laboratory's internal SOP have elapsed. Disposal shall be documented (e.g. in the refrigerator/freezer log) and shall contain a minimum of date of disposal, initials of the individual who discarded the sample, and sample

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number(s) or set number(s). Each laboratory shall establish the proper procedures for disposal (e.g., disposal by a licensed contractor) of its extracts in an internal SOP.

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- Specified acceptable sample weight ranges in Section 5.1.a
- Specified approximate temperatures in Sections 5.2.f, 5.2.h, 5.3.a, 5.3.b, 5.4.a, and 5.4.b

Revision 12

- Added reference to MPO Commodity Fact Sheets in Section 5.1.b
- Specified the receiving laboratory fax a copy of paper SIFs to MPO in Section 5.1.b
- Removed requirements for Sample Receipt Form (Attachments 1 and 2) from Section 5.1.i
- Specified the receiving laboratory notify the appropriate collection coordinator within five working days in Section 5.1.i
- Specified the receiving laboratory notify MPO of any continuing unresolved sampling issues on a monthly basis in Section 5.1.j
- Removed references to Sample Receipt Form from Section 3

Revision 11

• Changed Section 5.2.e to accommodate commodities stored at room temperature

Revision 10

- Removed requirement to document unusually large sample sizes on the Laboratory Information Form (LIF) from section 5.1.a (the documentation requirement is in SOP PDP-LABOP-03, section 5.1)
- Changed reference in section 5.1.h.2 to reflect new data SOP numbering
- Added Sample Receipt Form as Attachment 1 and directions for completing Sample Receipt Form as Attachment 2

Revision 9

• Specified laboratory holding time requirements for sample homogenization are from sample receipt in subsections 5.2.d and 5.2.g